ABSTRACT

Based upon a strong correlation between regulator T cells (Treg cells) and suppressing or preventing a cytotoxic T cell response, provided are methods for the production of *ex vivo* activated and culture-expanded isolated $CD4^+CD25^+$ suppressor Treg cells for the prevention or suppression of immune reactions in a host, particularly in a human host, and including autoimmune responses. The resulting *ex vivo* culture-expanded Treg cells provide a sufficient amount of otherwise low numbers of such cells, having long term suppressor capability to permit therapeutic uses, including the preventing, suppressing, blocking or inhibiting the rejection of transplanted tissue in a human or other animal host, or protecting against graft vs host disease. Also provided are therapeutic and immunosuppressive methods utilizing the *ex vivo* culture-expanded Treg cells for human treatment, and high efficiency methods for research use.